GMA Group of Medical Advisers

GCM Groupe des conseillers médicaux

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GMA REPORTS

Since the 1950's, the Atomic Energy Control Board (AECB) has made use of advisory committees of independent experts to assist it in its decision-making process. In 1979, the Board restructured the organization of these consultative groups, resulting in the creation of two senior-level scientific committees, the Advisory Committee on Radiological Protection (ACRP), and the Advisory Committee on Nuclear Safety (ACNS). A third body of advisers, known as the Group of Medical Advisers (GMA), is composed of medical practitioners licensed under the laws of the province in which regulated nuclear activities are situated. Medical Advisers are nominated by the appropriate department or agency and appointed by the Board pursuant to the *Atomic Energy Control Regulations*. They make recommendations to the Board respecting, inter alia, the medical examination of atomic radiation workers, medical surveillance required as a result of overexposures, and medical aspects of emergency plans.

From time to time the GMA issues reports which are normally published by the AECB and catalogued within the AECB's public document system. These reports, bound with a distinctive cover, carry both a group-designated reference number, e.g. GMA-1, and an AECB reference number in the "INFO" series. The reports generally fall into two broad categories: (i) recommendations to the AECB on a particular medical topic, and (ii) background studies. **Unless specifically stated otherwise, publication by the AECB of a report prepared by the Group of Medical Advisers does not imply endorsement by the Board of the content, nor acceptance of any recommendations made therein.**

RAPPORTS DU GCM

Depuis les années cinquante, la Commission de contrôle de l'énergie atomique (CCEA) fait appel à des comités consultatifs composés d'experts indépendants pour l'aider dans ses prises de décisions. En 1979, la CCEA a restructuré l'organisation de ces groupes de consultation pour former deux comités scientifiques supérieurs, le Comité consultatif de la radioprotection (CCRP) et le Comité consultatif de la sûreté nucléaire (CCSN). Un troisième groupe, le Groupe des conseillers médicaux (GCM), est formé de médecins agréés pour la pratique de la médecine en vertu des lois de la province dans laquelle se tiennent des activités nucléaires réglementées. Le ministère ou l'organisme compétents proposent le nom de conseillers médicaux qui sont ensuite nommés par la CCEA en vertu du *Règlement sur le contrôle de l'énergie atomique*. Ces conseillers font des recommandations à la CCEA concernant, entre autres, l'examen médical des travailleurs sous rayonnements, la surveillance médicale nécessaire en cas de surexposition et les aspects médicaux des plans d'urgence.

Le GCM rédige à l'occasion des rapports qui sont normalement publiés par la CCEA et catalogués dans sa collection des documents publics. Ces rapports se présentent sous une couverture distincte et portent un numéro de référence propre au comité (GCM-1, par exemple), ainsi qu'un numéro de référence de la CCEA dans la série «INFO». Ils se divisent habituellement en deux catégories générales : i) les recommandations présentées à la CCEA au sujet d'une question médicale particulière; ii) les études générales. **À moins d'indication contraire, la publication par la CCEA d'un rapport du Groupe des conseillers médicaux ne signifie pas qu'elle en approuve le contenu, ni qu'elle en accepte les recommandations.**

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GMA-13

REVIEW OF QUALITY ASSURANCE IN RADIATION THERAPY

by the

Group of Medical Advisers to the Atomic Energy Control Board

May, 1998

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EXECUTIVE SUMMARY

In Canada, there are clearly defined safeguards for workers and members of the public who are exposed to radiation from external beam radiotherapy devices and sealed brachytherapy sources. On the other hand, effective measures to ensure patient safety in the delivery of radiation therapy are not applied uniformly in Canadian centres. Instead, reliance is placed upon the application of commonly accepted safety practices and upon the training of the professional staff. The Group of Medical Advisers (GMA) to the Atomic Energy Control Board (AECB) expressed concern that levels of quality assurance in radiation therapy were shown to vary across the country. The GMA undertook to review quality assurance in radiation therapy centres and make recommendations concerning the measures required to achieve a uniform national system.

The rationale and justification for any quality assurance program in medicine is to ensure that the patient is protected from accidents or misadministrations by establishing safeguards that will either prevent the misadministration or detect it at an early stage. Radiation can be considered a hazardous drug, and patients undergoing radiation therapy might well expect to have safeguards introduced for their protection. The public also expects health agencies to be accountable.

At present, there are no formally agreed national standards for radiation therapy quality assurance in Canada. Over 80% of the radiation therapy centres surveyed in Canada currently have some type of quality assurance program in place, but these programs vary widely. There is a clear need to establish national standards for radiation therapy quality assurance. The standards will increase the credibility of the radiation therapy process, will demonstrate accountability in the system, will decrease legal liability and will set a common format for data collection. It would appear that a national organization independent from the cancer centres would be best placed to address issues of patient safety in an unbiased manner. Either voluntary quality assurance guidelines or mandatory regulations could be used to achieve national uniformity.

In Canada, there are no reliable data on the number or severity of misadministrations in radiation therapy. To gather this data the GMA suggests that a database of significant events be established. The frequency of significant events and the need to continue national monitoring of all incidents should be assessed by performing a risk analysis based upon data collected over an extended period of time from all radiation therapy centres. In this report, *Recordable* events are defined as any loss of control of a system involved in the delivery of a prescribed radiation dose. *Reportable* events form a subset of the total and are defined as those events which result in a major misadministration. Criteria for *Recordable* and *Reportable* events are proposed in the text of the report but the final definitions are left to national professional bodies. A reporting mechanism will allow important information that might affect patient safety to be disseminated without delay. National standards and a national database of significant events and risks should be established.

Following a review of the national situation, the GMA recommends that a national program in quality assurance should be implemented and adopted by radiation therapy centres in a phased approach as follows:

PHASE I

To ensure that radiation therapy centres in Canada have a common basis for establishing and evaluating their quality assurance programs it is recommended that professional bodies which represent radiation oncologists, medical physicists and medical radiation technologists be asked to develop national standards for radiation therapy quality assurance and to elaborate a uniform quality assurance program to be adopted by all radiation therapy centres.

This phase would include the dissemination of the standards and the establishment of a quality assurance program by each radiation therapy centre, based upon the recommended standards. A peer review program to audit compliance with the national standards should be established, and if necessary, compliance with the national standards can be made a condition of the Atomic Energy Control Board licence.

PHASE II

In this phase a mechanism will be established to develop and maintain a national database of reportable events and risks. The agency responsible for maintaining this database and the means for disseminating the information will need to be decided. Measures must be taken to ensure that patient records are protected and remain strictly confidential. Specifically this phase will include:

a) the establishment of a log book of all *Recordable* events at each radiation therapy centre which is submitted to a central organization on a regular basis for data collection and analysis;

b) the establishment of an electronic bulletin board for the dissemination of information regarding *Reportable* events and risks to radiation program directors, heads of medical physics and radiation therapy, and others, at all radiation therapy centres in Canada.

The Canadian Institute for Health Information (CIHI) should be investigated as the potential provider of the services in a). The Canadian Organization of Medical Physics should be approached with regard to b).

PHASE III

Phase I should be started as soon as possible. Phase II should begin as soon as national standards have been set by the professional bodies. It is expected that development of standards and the establishment of a national database will take at least 2 years. When these are in place Phase III would begin and would involve a risk analysis based upon submitted data on *Recordable* and *Reportable* events. Specifically Phase III will include:

a) after a minimum of two years data collection, a risk analysis of submitted *Recordable* and *Reportable* events by CIHI or another national agency;

b) a review of the risk analysis and compliance results by professional organizations and other stakeholders to determine if the quality assurance standards are appropriate and if continued national data collection for *Recordable* events is necessary.

PHASE IV

If continued data collection is considered justified on the basis of this risk analysis, Phase IV should be implemented, and would involve the establishment of a permanent national database of *Recordable* events. In addition, there would be a review of the adequacy of the national standard to ensure that the risks identified are being correctly addressed.

Two other significant issues were identified by the GMA in their review of Quality Assurance in Radiation Therapy:

- There is a need to rationalize the licensing and monitoring system for radiation equipment so that one single standard of safety and one licensing procedure is used for all equipment which produces or uses radiation in the treatment of patients;

- Much of the risk to the patient that is associated with the process of radiation therapy is due to ancillary equipment which may be complex and is often computer controlled. The risks due to failure or misuse of this equipment should be assessed and a system should be put in place to provide type approval for this equipment before it can be purchased by a radiation therapy centre.

The GMA recommends that these issues be addressed by the AECB and, if necessary, in collaboration with Health Canada.

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1. INTRODUCTION

1.1 Purpose and Scope

In Canada, there are clearly defined safeguards for workers and members of the public who are exposed to radiation from external beam radiotherapy devices and sealed brachytherapy sources. On the other hand, effective measures to ensure patient safety in the delivery of radiation therapy are not applied uniformly in Canadian centres. Instead, reliance is placed upon the application of commonly accepted safety practices and upon the training of the professional staff. The Group of Medical Advisers (GMA) to the Atomic Energy Control Board (AECB) expressed concern that levels of quality assurance in radiation therapy were shown to vary across the country. The GMA undertook to review quality assurance in radiation therapy centres and make recommendations concerning the measures required to achieve a uniform national system.

1.2 Historical Background

The AECB regulates radiation doses received by the public and by workers exposed to radiation from radionuclides and from medical linear accelerators with energy equal to or greater than 10 MeV. For patients requiring radiation as treatment, there is no similar surveillance. There is no single body responsible for collecting and recording data on accidents or misadministrations in radiation therapy. There is no national organization responsible for quality assurance in radiation therapy. The AECB has traditionally kept away from any patient-related legislation [AE82]. The fact that patient safety in medical exposure to ionizing radiation was not regulated like worker and public radiation exposure, was discussed by the AECB in 1993 [AE93].

The AECB gave two updates on patient safety [AE94b, AE94c] and described a plan of action. This included a request for information and comments in the AECB Reporter from licensees, who were individually sent letters in the summer of 1994 [AE94e], and discussions with the United States Nuclear Regulatory Commission (USNRC) [AE94d]. A research contract initiated by the GMA was awarded to review quality assurance in Canadian radiation oncology centres and nuclear medicine departments and resulted in the COMPAS report [MA95]. The recommendations from this report are listed in Appendix B. Some of the recommendations of the COMPAS report are similar to the recommendations from the GMA in this report.

Replies to the request in the AECB Reporter article from licensees on patient safety in radiation therapy are briefly summarized in Appendix A. Input from patients and members of the public was not sought. The recommendations covered the extremes between no more regulation and detailed regulation of patient safety in radiation therapy.

As a result, the GMA undertook to examine the question more thoroughly.

1.3 The Size of the Problem

The USNRC reported that the frequency of misadministration and abnormal occurrences for therapeutic administrations in 1990 was approximately double the average number for the previous years. The causes of these misadministrations and abnormal occurrences are listed as: insufficient supervision, deficient procedures or failure to follow procedures, inattention to detail and inadequate training [NR91]. While these statistics may not be strictly applicable to Canada, it is likely that the causes encountered here are similar. Radiation accidents involving therapy equipment have occurred in Canada, but there is no regulatory body to which they must be reported [AE93, AE94a, HA97], even though incident reporting is considered to be an important part of quality assurance.

It is difficult to estimate the severity and frequency of accidents or misadministrations throughout the country. In many radiation therapy centres, significant misadministrations, which are variably defined, are logged locally as incident reports and are not filed separately from other reported workplace incidents. This makes it difficult to retrieve the data needed to arrive at an accurate incidence of radiation therapy misadministration. Ontario is the only province that has regulated the use of radiation in medicine (the Healing Arts Radiation Protection (HARP) Act), to date. In the United States, the risk of death as a result of therapeutic radionuclide misadministration has been estimated at 0.0006% (6×10^{-6}). Also, the USNRC quotes a rate of 30 per 100,000 administrations for errors that result in "significant side effects" [NR94]. In the United Kingdom, there is some progress towards the institution of voluntary national incident data recording in the delivery of all forms of radiation therapy [Wi96].

The USNRC regulates only approximately one-fourth of all radiation therapy treatments in the US. Recently the Institute of Medicine (IOM) of the U.S. National Academy of Sciences has undertaken an independent review and evaluation of the USNRC's Medical Use Program, which oversees the regulation of reactor-generated by-product material. The review was intended to complement an internal management review already under way within the USNRC [IM96]. The conclusions of these reviews were controversial and the debate continues. No review was undertaken on the US Agreement States Medical Use Program (State Governments in the US who administer radiation control activities). Both the USNRC and the US Agreement States Program have a licensing requirement for reporting radiation therapy misadministration.

Major accidents in radiation therapy have occurred world-wide [Ro96, Appendix C, IA]. Although these occurrences have been infrequent, they highlight the need to implement quality assurance programs that are designed to prevent errors, to recognize and correct faults early, to diagnose causes and to disseminate this information to avoid repetition of the same accident at a different centre. In the USA, the Centre for Devices and Radiological Health of the Food and Drug Administration (FDA) operates Medwatch, a voluntary reporting program for incidents involving radiation therapy equipment.

Also, the distinction must be made between random errors which occasionally lead to large errors in dose delivery and more subtle systematic errors which may lead to much smaller errors in dose but which may affect very large groups of patients. Quality assurance programs must be designed to minimize the occurrence of random errors but also to eliminate large systematic errors in dose

delivery which may significantly increase normal tissue complications or decrease survival for large cohorts of patients.

1.4 Definition and Scope of Quality Assurance

There are many different terms used in discussions regarding quality assurance. Quality control implies a systematic approach to monitoring performance. It deals with procedural practices and is an element of quality assurance. In some systems, quality management is synonymous with quality assurance. In this report it was felt necessary to be clear on the definition of quality assurance and therefore what exactly will be assessed in the review process.

The definition of quality assurance from the International Organization for Standards (ISO) is concise, generic and defined as:

> "All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality" [IS87].

However, in carrying out its review, the GMA has recognized that there are several distinct ionizing radiation technologies in medical institutions. In this report, the following definition of quality assurance in radiation therapy, taken from the World Health Organization has been used instead:

> "All those procedures that ensure consistency of the medical prescription and the safe fulfilment of that prescription as regards dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel, and adequate patient monitoring aimed at determining the end result of treatment" [WH88].

The main rationale and justification for any quality assurance program in medicine is to ensure that the patient is protected from accidents or misadministration by establishing safeguards that will either prevent the misadministration or detect it at an early stage. This may minimize the morbidity of the affected patient and potentially spare subsequent patients receiving the same treatment. Radiation could be considered a hazardous drug, and thus patients undergoing radiation therapy should expect to have regulations for their protection. The public also expects health agencies to be accountable. At present, effective safeguards are not uniformly present in the more than thirty radiation therapy centres, and a high degree of reliance is placed upon professional training and upon the application of common safety practices.

Many national and international bodies have generated reports addressing quality assurance in radiation therapy. The American Association of Physicists in Medicine (AAPM) has detailed a comprehensive program for quality assurance in radiation oncology in its Task Group 40 report [MP94a]. This document recommends a structure for the program and gives details of the quality control to be performed. The report of AAPM Task Group 45 [MP94b] lists detailed commissioning and acceptance procedures for linear accelerators and the report of Task Group 56 [MP97] details a quality assurance program for brachytherapy. The Task Group 35 report discusses linear accelerator safety, incident reporting and operator training [MP93]. The World Health Organization in its 1988 report on quality assurance in radiotherapy outlined the elements of a comprehensive quality assurance program and gave details of expected quality control [WH88]. The United Kingdom

Department of Health issued recommendations which are based upon the ISO formalism in its 1991 report. This report is presented as a quality standard to provide a formal system for managing quality in radiation therapy. The emphasis in this report is on quality requirements, not on the quality control required to maintain those requirements [UK91]. A broad set of recommendations for quality assurance in the European Radiation Oncology community has recently been presented by Thwaites [Tw95].

In Ontario, the Radiation Therapy Advisory Committee recommendations to the HARP Commission address the need for common standards in equipment, procedures and qualifications of personnel involved in the delivery of radiation therapy [HA97]. One of its recommendations is the establishment of local quality assurance committees to collect and review copies of incident reports which relate to radiation therapy and report these to the facility's Chief Executive Officer (CEO) along with recommendations for remedial action. The CEO in turn submits an annual report to the HARP Commission which will also organize on-site surveys of each facility on a regular basis.

ACRP-16 [AC97] provides general guidance on the creation and improved administration of a good radiation safety program in hospitals and academic institutions. Its emphasis is almost entirely upon the protection of workers; issues such as misadministrations to patients are not addressed. This document addresses these issues and others associated with the implementation of quality assurance programs.

In summary, the literature contains a wide spectrum of recommendations ranging from very high level recommendations on the structure and reporting mechanisms for quality assurance programs to the details of quality control procedures for specific equipment.

1.5 Issues

After reviewing all comments submitted in response to surveys by the AECB and GMA (Appendix A) and the COMPAS report [MA95], the GMA has identified several major issues which must be considered before the establishment of a national quality assurance program for Canadian radiation therapy centres. These are:

- resolution of jurisdictional issues in the licensing and regulation of radiation therapy equipment
- the cost-benefit analysis of setting up a national database and a quality assurance monitoring program
- the avoidance of duplication in data collection
- the need to maintain confidentiality of patient records
- the problems with monitoring compliance and the need for an independent agency
- the need to respect professional standards
- the resources required for new quality assurance initiatives
- the need to avoid impeding research and development activity

1.5.1 Jurisdictional Issues in Licensing and Regulation

In Canada there are multiple jurisdictions involved in the regulation of equipment for radiation therapy. To set standards for a national quality assurance program for radiation therapy, federal and provincial regulations for health, labour, atomic energy and transportation must be considered. At present the federal and provincial governments share responsibility for health and labour matters. The federal government is responsible for the establishment of Canada-wide standards and the provinces administer the operational programs to meet those standards. Health Canada is responsible for the importation and sale of all radiation emitting devices, but after such equipment is purchased, its use becomes the responsibility of the provinces. The federal government alone sets regulations for the handling, storage and disposal of radionuclides and is also solely responsible for regulating the transportation of radioactive materials. It could be questioned whether federal agencies, such as the AECB or Health Canada, should be involved in setting standards in radiation therapy quality assurance. As the provision of health services is a provincial jurisdiction, it should perhaps also be a provincial responsibility.

Federal legislation which is pertinent to radiation therapy includes:

1. The Atomic Energy Control Act - 1946 (AEC Act) and under this Act the Atomic Energy Control Regulations and the Transport Packaging of Radioactive Materials Regulations. (The AEC Act and Regulations will soon be replaced by the Nuclear Safety and Control Act and a set of regulations which include the Class II Nuclear Facilities Regulations and the Nuclear Substances and Devices Regulations.)

2. The Radiation Emitting Devices Act (1985) and the Radiation Emitting Devices Regulations.

3. The Food and Drugs Act and the Medical Devices Regulations.

Of most relevance to this report is the AEC Act and the Regulations under the Act. The AEC Act established the AECB to regulate the use of atomic energy so that it does not pose undue risk to health and safety. The AECB has jurisdiction over radionuclides used for teletherapy and brachytherapy, as well as for linear accelerators of energy equal to or greater than 10 MeV. The AECB fulfils this mandate with regard to medical linear accelerators by a system of guidelines, licensing and inspection. The AECB licences medical linear accelerators under Section 8 of the AEC Regulations because the definition of a nuclear facility includes a particle accelerator. By definition the AEC Regulations apply only to radiation therapy equipment capable of producing "atomic energy" as defined in the AEC Act. In practice this includes all medical linear accelerators of nominal energy equal to or greater than 10 MeV since these linear accelerators can produce the neutrons required for nuclear transmutations. Cobalt-60 units are licensed under Section 7 of the AEC Regulations since they contain more than 10 scheduled quantities of a radioactive prescribed material. In its activities the AECB places the primary emphasis on the safety of members of the public and radiation workers, rather than patient safety. The AECB grants operating licences for these machines after certain conditions, intended to protect workers and the public, are satisfied. Linear accelerators of energy less than 10 MeV are not regulated by the AECB.

The degree of provincial licensing and regulation of radiation emitting devices in radiation therapy varies significantly across Canada. In all provinces there is legislation to regulate the operation of diagnostic radiation equipment. In some provinces there is also legislation under the Occupational Health Act or equivalent to protect the operator of radiation equipment. However, licensing and regulation of the operation of radiation therapy equipment are not uniform. In some provinces, facility design and inspection for low energy linear accelerators is left completely to the medical physics staff of an individual centre. In others, design and commissioning data must be approved by provincial authorities, some of whom may not have sufficient technical resources to form an independent judgement and therefore rely on the advice of the licensees they are regulating.

Typically, radiation therapy centres have high energy, dual mode linear accelerators with at least one operating energy above 10 MeV, as well as other accelerators with a maximum energy of less than 10 MeV. In addition, the centres often have cobalt-60 treatment units, brachytherapy devices containing various radioisotopes, x-ray treatment units with energies up to 300 keV and planning x-ray units (simulators) with radiographic and fluoroscopic capabilities. In Ontario at present, dual mode accelerators, cobalt-60 units and brachytherapy devices are all licensed by the Materials Regulation Division of the AECB, but each device has different requirements for the end user since they fall under different sections of the AEC regulations. The low energy accelerators, x-ray treatment equipment and simulators are registered (but not licensed) with the x-ray inspection services of the Ministry of Health and must meet the Regulations under the HARP Act (1984). These regulations were written primarily for diagnostic x-ray equipment and contain many sections that are inappropriate for therapy equipment or simulators. The inspection programs under the federal and provincial authorities are quite different and the requirements for maintenance of either a licence or registration are different. In addition, some standards for radiation protection legislated under a provincial act sometimes differ from those promulgated under federal legislation.

Two quite different procedures are required to acquire and operate two types of equipment that carry similar risks to the patient, the public and the operators. In Canada the person responsible for the radiation safety program for AECB-regulated linear accelerators must be qualified to standards different than those for Ontario's provincially-regulated medical linear accelerators. The operation of the quality assurance program can be adversely affected by this split in jurisdiction. There could be a tendency to allocate resources in proportion to the legislated requirements for specific equipment as opposed to a system based upon risk analysis. Also, there is a danger that risks will be assessed for each group of equipment separately and the cumulative risk may not be assessed.

In addition to the inconsistencies noted above, there are gaps in the coverage of the existing legislation and guidelines. The AECB emphasizes the safety of members of the public and equipment operators in the design of its guidelines and regulations. Some provincial legislation such as the Ontario HARP Regulations are written with the emphasis on patient safety but similar legislation is not in place across the rest of the country.

In summary, there is no consistent set of requirements for the acquisition, installation and operation of all radiation therapy equipment in Canada. The monitoring of radiation safety programs is uneven, and patient, worker and public safety issues are not dealt with in a comprehensive fashion.

Recommendation 1:

> **There should be a single Canadian body empowered to licence and monitor the use of all radiation therapy treatment and simulation equipment in Canada. If existing regulatory bodies are used, their efforts must be coordinated and extended.**

1.5.2 Cost-Benefit Analysis of Setting up a National Database and Quality Assurance Monitoring Program

To decide upon the scope of any national effort to investigate, recommend, organize and monitor quality assurance in radiation therapy it would be useful to have a complete cost-benefit analysis to support actions taken. The costs of setting up a national quality assurance program can be ascertained but the benefits can only be determined if assumptions are made about the risks associated with maintaining the status quo. No data on the frequency and morbidity of radiation therapy misadministrations has been collected in Canada and it might be assumed that the lack of a national quality assurance program does not pose a significant risk to health or mortality. In the absence of data it is not possible to determine if the benefit to society justifies the cost of organizing an ongoing review of radiation therapy quality assurance programs.

1.5.3 Duplication in Data Collection

Individual radiation therapy centres may already have good quality assurance programs, and the duplication incurred by the imposition of a national quality assurance monitoring program could well increase the cost without any significant benefit.

1.5.4 Confidentiality of Patient Records

It is essential that information collected is not linked to individual patients so that confidentiality of patient data can be maintained. The intent is not to withhold information from patients but to maintain patient anonymity.

1.5.5 Monitoring Compliance

Monitoring compliance is normally one of the most problematic areas of a quality assurance program. There is resistance in the radiation therapy community to having a standing group of inspectors who would review the details of treatment centre quality assurance programs on a regular basis. Most professionals would not object, however, to a brief review of quality assurance as part of an existing accreditation process. If detailed monitoring is required it will be time consuming and must be carried out by qualified experts; this has implications for costing. Compliance can only be determined once standards have been established. At present, it would only be possible to assess the degree of uniformity of dose calibration which is an important, but small part of the overall quality assurance program.

Compliance monitoring, if it is necessary, should be organized by a national body independent of the radiation therapy centres. It is not clear which group could or would take on this responsibility although some suggestions are given in this document.

1.5.6 Professional Standards

The professional and medical responsibilities of radiation oncologists in the care of their patients should be respected. Their standards of practice are monitored by the Royal College of Physicians and Surgeons of Canada and provincial Colleges or Medical Associations. Therefore, any radiation therapy quality assurance regulations should only relate to the delivery of radiation in an amount and frequency already determined by a radiation oncologist. In addition there are provincial colleges regulating and monitoring the practice of radiation therapists. The standards of these and of all professional groups must be considered and respected in the formulation of national standards.

1.5.7 Resources Required for New Quality Assurance Initiatives

Estimates of manpower required for quality control procedures on radiotherapy equipment can be obtained from the literature. Most radiation therapy centres do have quality assurance programs and do have staff performing quality control. It is not anticipated that the adoption of Canadian standards will have a significant impact on resources required at the radiation therapy centres. There may be an initial time and manpower requirement to put the necessary quality assurance structure and documents in place, if these do not already exist, but the GMA anticipates that for the majority of radiation therapy centres the standards will be able to be met with existing staff.

1.5.8 Research

The innovative use of new equipment and techniques to improve radiation therapy delivery could be hampered by overly restrictive regulatory controls. Care must be taken to ensure that such research will not be impeded.

2. THE ADMINISTRATION OF THERAPEUTIC RADIATION BY EXTERNAL BEAM AND SEALED SOURCES

2.1 Introduction

Radiation therapy is an effective modality for the treatment of cancer, and may be used as the principle treatment or in conjunction with surgery and/or chemotherapy.

Radiation therapy may be delivered by an external beam, by the use of sealed radioactive sources placed close to or within body tissues, or from an injection of radioactive substance into the blood stream of the patient. This discussion will be limited to external beam and sealed source irradiation.

In addition, radiation therapy can also be used in the treatment of selected non-malignant disease. Neurosurgeons for example, have found stereotactic external beam therapy to be beneficial in the treatment of arterio-venous malformations of the brain, and sealed source radiation therapy has been

used by cardiologists to prevent re-stenosis after coronary angioplasty. As most of these therapies are carried out in cancer treatment centres, such patients will be subject to the same quality assurance programs as those undergoing treatment for malignant disease. If in the future, such treatments are carried out elsewhere, a quality assurance program of the same calibre as that in a cancer treatment centre should be established.

2.2 External Beam Radiation Therapy

External beam radiation therapy usually involves photon beams. Occasionally, electron radiation and very rarely heavy particle beam radiation therapy are also used. Photon beams are produced from x-ray tubes, linear accelerators or from a mounted radioactive source of cobalt-60. Electron radiation is produced by linear accelerators and heavy particle beam therapy is produced by a cyclotron. There is only one facility in Canada which uses heavy particle beam therapy for treatment purposes, and this is carried out in an investigational setting.

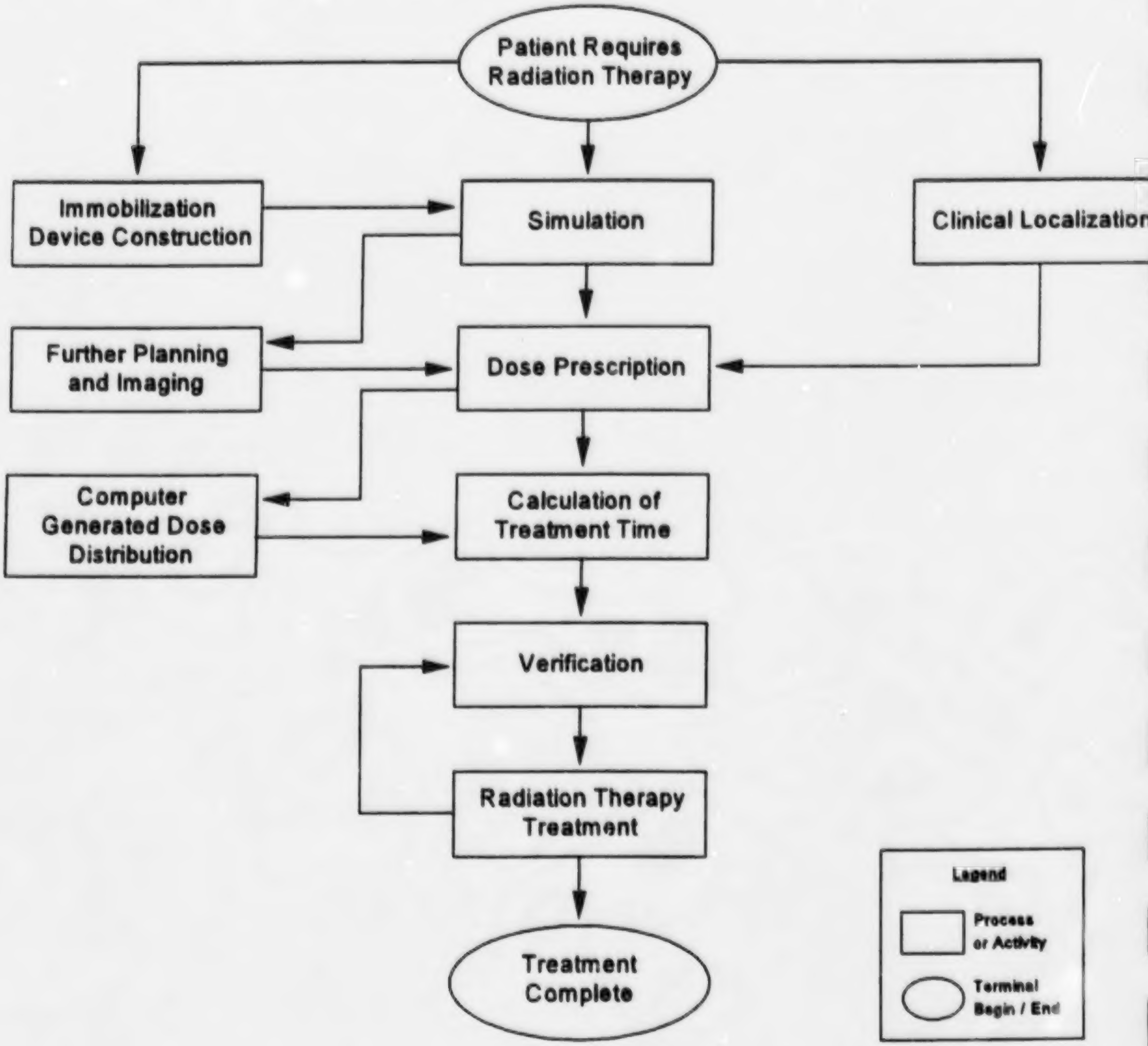
External beam therapy from linear accelerators is the most common type of radiation therapy in Canada. Before patients are treated, radiation therapy planning occurs. This may involve the use of a simulator, which is essentially a fluoroscopic device that reproduces the dimensions of treatment beams and helps the radiation oncologist localize the target volume. After this process, marks are drawn on the patient's skin, occasionally augmented by pin-prick tattoos. At this point, most patients can be treated on the linear accelerator by aligning to the marks obtained at simulation. Simulation and planning may sometimes be carried further with diagnostic and planning tools such as a computed tomography or a magnetic resonance imaging scan. Radiation dose distributions are often generated in two or more dimensions with the aid of a treatment planning computer. Immobilization devices are employed during radiation therapy when it is essential that the patient not move during treatment. Before the first treatment and periodically during the treatment course, beam placement is verified with portal radiographs. Recent developments in precision radiation therapy require detailed target delineation in three dimensions often with the aid of a sophisticated workstation configured to manipulate volume data sets. With precision radiation therapy, computer controlled field shaping devices may be used to make the dose distribution conform closely to the target. The tolerances for this conformal treatment may be several millimetres or less, requiring precise patient positioning and beam definition, increased verification of geometry and increased quality control. The schema of the external beam radiation therapy process is illustrated in Figure 1.

Errors may occur in the localization and treatment of the tumour due to incorrect positioning of the patient or the incorrect use of set-up points. Misadministrations in dose delivery can occur due to machine miscalibration, hardware failure, software failure in treatment planning or delivery, improper patient positioning on the treatment unit, improper placement of accessories, or incorrect linear accelerator settings.

2.3 Sealed Source Radiation Therapy

Sealed source therapy involves the insertion or implantation of radioactive sources into or close to the tumour mass. It has the advantage of delivering a high local dose, but may pose significant problems in the protection of staff and the public from radiation exposure.

Figure 1. External Beam Radiation Therapy Process



To avoid exposing staff to the radioactive sources, inert hollow applicators have been designed for insertion into body cavities or implantation into tissues prior to being loaded with high activity sources. After the position of the applicators has been verified radiographically, the patient is transferred back to a shielded room on the hospital ward. The hollow applicators are subsequently loaded with radioactive sources. This approach has significantly reduced the radiation exposure to medical personnel. After a period of time, which has been calculated to deliver the prescribed radiation dose, the radioactive sources are removed from the patient, along with the applicators. The time required to deliver the radiation dose may be calculated manually from tabulated data or by using treatment planning computers to calculate dose distributions around implants or insertions. In some cases radioactive material is permanently implanted into a target volume. The schema of the sealed source radiation therapy process is illustrated in Figure 2.

Errors in treatment may occur from the movement of positioned sources or applicators, hardware failures, such as cable breakage in afterloading machines, the wrong configuration of sources, incorrect source calibration, dose miscalculations, software failures, or incorrect treatment machine settings.

3. SOME QUALITY CONTROL PROBLEMS IN RADIATION THERAPY

3.1 Major Problems in Canadian Radiation Therapy Quality Assurance

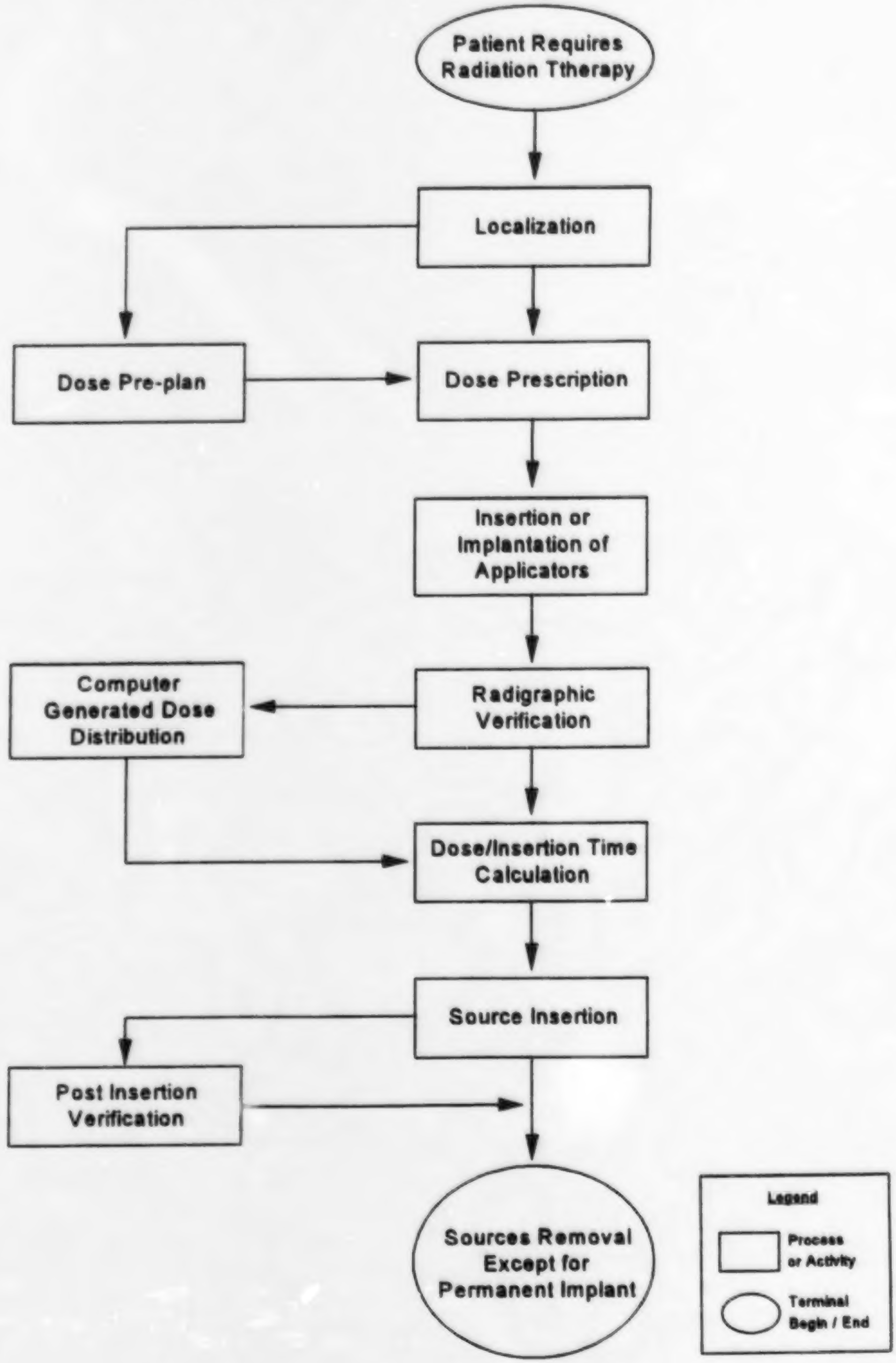
After reviewing the existing quality assurance procedures and programs in place in Canadian radiation therapy centres the GMA has identified several problems with existing practice. These include:

- the lack of national standards in radiation therapy quality assurance
- the lack of a monitoring (quality audit) program for quality assurance in radiation therapy centres
- the lack of a national database of actual and potentially significant incidents
- the lack of regulation and monitoring of the safety of ancillary equipment used in radiation therapy.

3.1.1 <u>National Standards</u>

The starting point for any national program in quality assurance must be the establishment of common, accepted standards. The standards should be broad based and should address the structure of proposed quality assurance programs, accountability for quality assurance, standards for equipment quality control, and standards for incident reporting. Existing international standards should be reviewed, together with existing formal (i.e., HARP) and informally adopted Canadian standards. The details of quality control procedures are adequately described in other publications which should be referenced in the standards document.

Figure 2. Sealed Source Radiation Therapy Process



Standards are best developed by experts in the field. A group of experts in radiation treatment, including radiation oncologists, medical physicists and radiation therapists should be organized to develop the Canadian standards. It is important, however, that a national statement of these standards be presented by a group independent of cancer treatment centres. The standards should therefore be maintained and promulgated by a national body such as the Canadian Association of Radiation Oncologists, which is not associated with individual cancer treatment centres.

National standards will provide a template for all radiation therapy centres to follow and a benchmark for evaluating quality assurance procedures. The standards will increase the credibility of the radiation therapy process, demonstrate accountability in the system, decrease legal liability, and standardize incident reporting.

Recommendation 2:

> **A group of experts should be appointed to develop Canadian Standards for Quality Assurance in Radiation Therapy based upon existing accepted standards. The standards should be maintained and promulgated by a group such as the Canadian Association of Radiation Oncologists.**

3.1.2 <u>A Monitoring Program - Quality Audits</u>

Some elements of the quality assurance programs at some cancer centres are subject to external audit, but this is not uniform. For example, primary calibration and other dosimetry data for teletherapy equipment is verified by the U.S. based Radiological Physics Centres (RPC) for centres that have patients registered in clinical trials conducted by the U.S. Radiation Therapy Oncology Group (RTOG). In most cases, however, the entirety of the quality assurance program at a treatment centre is not reviewed by an external agency. Although there is a sense that dosimetry and planning data is accurate to within acceptable limits in Canada, there is no data to verify this assumption. Also, there is not a measure of compliance to professionally accepted standards such as the AAPM's Report of Task Group 21. The Canadian standards should contain a requirement for an external peer audit of the compliance to the quality assurance standards once these have been developed and promulgated. Monitoring is best done by a group of experts in radiation therapy which is independent of cancer treatment centres. If necessary, the standards can be integrated with existing licencing procedures for radiation therapy centres.

Recommendation 3:

> **A peer auditing process should be developed to monitor compliance with the Canadian Standards for Radiation Therapy Quality Assurance.**

Recommendation 4:

If necessary, compliance with the Canadian Standards for Radiation Therapy Quality Assurance should be made a condition of the licence issued by the Atomic Energy Control Board to radiation therapy centres.

3.1.3 The National Database

There is great value in reporting incidents or potential incidents so that other practitioners can benefit from this knowledge and change their practice accordingly and thereby minimize the risk of treatment misadministration.

Misadministration incidents which result in patient injury can often be traced to improper or unconventional equipment usage or to a particular machine design fault. These incidents may be reported locally although the criteria for incident reporting are not uniform across the country. There is a requirement to report incidents to the AECB but only for incidents that relate to AECB-regulated devices and only when there was a significant chance that the incident resulted in a radiation overexposure to a worker or a member of the public.

There is a need for widespread, uniform communication of all incidents resulting in patient injury or radiation misadministration. Also, there is a need to disseminate information on equipment design flaws that have the potential to cause significant patient injury or radiation misadministration.

At present, the FDA in the United States administers a database of all equipment related incidents and potential design problems for both diagnostic and radiation treatment equipment. Updates of this database are regularly communicated to the appropriate centres using Medwatch. In Canada there is no formal mechanism for gathering or transmitting information of this type. Health Canada operates a voluntary medical devices problem reporting system called the Medical Devices System. Reporting of radiation therapy incidents has been poor. Many Canadian users rely on the U.S. database, manufacturers' information, the limited equipment notices from the AECB, or word of mouth from other users. Often informal user networks are established to distribute information about a specific device. Although any system of incident and risk reporting will rely on the diligence of the reporters and may therefore be incomplete, a common national database of this information will reduce the risks associated with inappropriate use and poor design of radiation treatment equipment. The data should be maintained and distributed electronically. The Canadian Organization of Medical Physicists (COMP) should be considered for the gathering and dissemination of this information.

Recommendation 5:

An electronic bulletin board should be established to disseminate information about significant incidents and risks in radiation therapy. A group such as the Canadian Organization of Medical Physicists should maintain this facility.

3.1.4 Regulation and Safety of Ancillary Equipment

The radiation therapy process includes several key sub-processes where errors or equipment malfunction could lead to a significant misadministration of radiation. Also, the radiation therapy equipment itself now often has independently controlled accessories that affect the radiation beam properties. In most cases, the operation of this equipment and these accessories is software controlled. Examples of major ancillary equipment include radiation therapy planning systems and radiation therapy simulators, including computerised tomography simulators. Major accessories to therapy units include multi-leaf collimators and electronic portal imaging devices.

Normally, all patients to be treated with external beam radiation have the parameters of their treatment partially decided at the treatment simulator. Approximately half of all patients have a computerized dose distribution and subsequent calculation of treatment unit settings. A single software error in the computer used for planning could affect a significant proportion of the patients receiving radiation therapy. There have been several reported incidents of treatment errors caused in this way.

Quality assurance of computer software is a complex problem and one that cannot be dealt with by the end user [MP94a]. Most of the major equipment used in radiation therapy is computer controlled, yet there is no national policy to monitor this equipment at the manufacturing stage. In the United States, partially in response to several fatal treatment errors involving computer controlled linear accelerators, there is now a rigorous system of compliance and approval which manufacturers must follow before being allowed to market or sell their product in the United States. In order to export their products, manufacturers must obtain certificates of approval from the regulatory authority of the importing country. This system, administered by the United States FDA, applies to all equipment where failure might pose a significant risk to the patient. In Canada, there is no such policy and non-U.S. manufacturers are potentially free to market and sell products in Canada that are prohibited for sale elsewhere.

A comprehensive strategy of equipment quality assurance must include a system to ensure that the safety of therapy equipment and ancillary and accessory equipment is controlled at the source.

Recommendation 6:

> **A system should be developed or adopted to ensure the safety of all equipment, including ancillary and accessory equipment, before it reaches the end user, if a failure of that equipment would pose a significant threat to patient safety.**

3.2 Some Sources of Significant Error in Radiation Therapy

To formally assess the risks associated with errors in radiation therapy, a detailed risk analysis should be undertaken and this analysis is recommended in this report. This analysis would highlight areas where quality assurance resources should be concentrated and would set the priorities for the quality assurance program. It would include a statement of the risks to the patient from a radiation therapy misadministration and a summary of the probabilities of such incidents occurring. Although there is

very little data on the frequency of misadministrations in radiation therapy, a recent report provides some insight into the major causes of error and the impact of these errors [Ro96]. Also, there are now many internationally recognized protocols to provide guidance for hazard assessment and quality control protocols for radiation therapy equipment [MP94].

Recommendation 7:

> **Data should be collected from all Canadian radiation therapy centres and analyzed to determine the frequency and severity of misadministrations in Canada. This database should be established and the analysis conducted by the Canadian Institute of Health Information.**

A brief review of some of the causes of errors in radiation therapy and examples of how these errors are handled will demonstrate the system now in place. This list is not meant to be comprehensive but is meant to highlight possible problems with present quality assurance measures.

3.2.1 Miscalibration of the output of a radiation therapy unit

An error in machine calibration will affect the treatment of every patient. It may be (and has been) caused by an error in calibration procedure or by faulty calibration equipment. Medical Physicists have agreed to follow common standards for the calibration of high energy units but there is no Canadian standard for the frequency of calibration of treatment units nor for checking calibration instrumentation.

The probability of occurrence for miscalibration is low so the frequency of output monitoring is relatively low. On some treatment units such as cobalt-60 machines the primary calibration may only be checked once per year. The impact of a miscalibration, however, can be very large as noted above. The quality assurance measures taken to verify the output normally include redundant measurements by certified medical physicists and an external audit of the measurements. When an error is discovered there is a review of all treatments which have been given on the unit and a suspension of all further treatment, until the error has been corrected.

3.2.2 Equipment failure leading to an error in treatment delivery

Poor maintenance procedures: There have been reported incidents of major treatment errors resulting from the incorrect repair or maintenance of radiation therapy equipment. The most common cause of equipment miscalibration is incorrect parameter setting during or after a maintenance procedure. There is no standard for the qualifications of repair personnel or for the quality control procedures which should be followed after a maintenance or service event.

Software errors: Treatment equipment is increasingly computer controlled. It is not possible for the user to completely check the software which controls the mode of operation of the unit. There have been several fatal accidents reported due to control software errors but there is not an agreed quality control procedure which might address this issue.

3.2.3 Treatment errors due to incorrect data being used in the planning procedure

The algorithms used to calculate the distribution of radiation dose in the patient are often complex and the computer software code itself is often not available to the end user. In addition, many centres use in-house software for some dosimetry procedures. Thus, for a moderately sized radiation therapy centre, with more than 4 treatment units, the amount of dosimetry data is considerable and the database itself is constantly being updated, or changed as new equipment is commissioned, new beam modifiers are introduced or the capabilities of the treatment unit are altered. There is a significant risk that inappropriate data may be used for a calculation. There must be a rigorous data control system in place to ensure that procedures for changing old data or introducing new data are well defined and safe. Also, there should be restricted access to the data files used on planning systems.

3.2.4 Errors due to miscommunication, inadequate or inappropriate procedures

An analysis of errors in radiation treatment [Os94] shows that most significant errors have multiple causes. One of the common causes is the failure to communicate instructions, data or descriptions correctly. Policies and procedures to govern the exchange of information were often not available or were not used. In an analysis of 7 misadministration events Ostrom [Os96] noted that all but one of the events were associated with a recent change in the procedure or some aspect of the procedure that was unique. In most cases adequate training and improved quality assurance programs would have prevented the error.

An error in treatment time or monitor unit setting for the treatment machine is quite common (approximately 2%). If this is not a systematic error, then the consequences are normally minor since it will affect only 1 patient and often only 1 field of several used to treat the patient. Since the probability of occurrence is high, the common practice is to check these calculations frequently, often several times for each field on each patient before treatment and several times during the course of therapy. The actions needed to correct such an error are often minor. The treatment technique is not altered, the overall treatment time is not changed and the patient is probably not notified.

For errors in treatment arising from any of the causes listed above there is not a uniform requirement for record keeping or for reporting internally or externally. Except for the adoption of the AAPM's report of Task Group 21 protocol by medical physicists for primary calibration of teletherapy equipment, there is no national standards for either the quality control procedures or resulting actions for any of the above error situations.

4. TOWARDS A SET OF NATIONAL RADIATION THERAPY QUALITY ASSURANCE STANDARDS - IMPLEMENTATION

The COMPAS report [MA95] discusses quality assurance in Canada in detail and shows that 83% of radiation therapy facilities have quality assurance programs of differing structure and function. There was no suggestion that the frequency of Reportable events was high. What was Reportable, and to whom, was variable. The ACRP-16 document [AC97] provides general guidance on the creation and administration of good radiation safety programs in medical and academic institutions but its emphasis is almost entirely on the protection of workers.

In contrast, there are reports that define standards for radiation therapy in Ontario [HA97], the World Health Organization [WH88], the United Kingdom [UK91], France [ES95], the United States [MP94] and Europe [ES95]. These reports discuss quality assurance and quality control in detail. Quality assurance can be far reaching, covering all aspects of the provision of radiation therapy services, or it may apply to one part of it.

The GMA believes that it is desirable for all patients to be able to receive a uniform quality in the delivery of radiation therapy services across Canada, and believes that it is possible to establish a mechanism that assures patient safety, and which at the same time ensures the independence of individual radiation therapy centres. It feels that this could be best accomplished with the following key components of a quality assurance program.

4.1 PHASE I - Standards and Auditing

4.1.1 <u>The Canadian Standards for Radiation Therapy Quality Assurance</u>

Phase I is the establishment of a set of Canadian standards for radiation therapy quality assurance and the elaboration of a uniform quality assurance program to be adopted by all radiation therapy centres. In the formulation of these standards it is recommended that existing standards from other jurisdictions be examined and adopted when possible. In particular it is recommended that the Ontario HARP Commission recommendations be reviewed for adoption nationally. It would not be wise to compound jurisdictional problems that already exist by introducing a two-tiered set of quality assurance guidelines in radiation therapy.

A team representing all of the professionals involved in the delivery of radiation therapy must develop the national standards. These individuals should be appointed by the appropriate professional bodies (i.e., radiation oncologists should be appointed by the Canadian Association of Radiation Oncologists (CARO)). In the formulation of the standards it is recommended that the team consult with the Canadian Council on Health Services Accreditation (CCHSA) to take advantage of their expertise with standards production. The professional team should present the completed standards to a national body responsible for maintaining and promulgating the national standards. It is recommended that a body such as the CARO be approached for this purpose.

It is not the intent to intrude into medical practice, or to review the qualifications of medical personnel which are governed by provincial boards and individual professional organizations, nor is it the intent to dictate individual facility treatment resources. However, once the decision to treat by radiation has been made, it is important to ensure a consistent and accurate fulfilment of the dose prescription delivered to the target volume.

The important elements of a set of national standards for radiation therapy quality assurance are:

1. The structure of the quality assurance program for each treatment centre including lines of accountability for quality assurance which extend to the governing body of the institution;

2. The scope of the quality assurance program for each treatment centre including lists of equipment, procedures and personnel that should be included under the program;

3. For primary calibration of teletherapy and brachytherapy equipment a statement of the protocol to be followed;

4. For all equipment and procedures included in the program, approved quality control protocols;

5. Requirements for documentation and records;

6. Requirements for auditing the quality assurance program;

Procedural elements which are viewed as essential to a quality assurance program in a radiation therapy centre include:

1. Each radiation therapy centre should have a quality assurance program and a procedures manual;

2. The prescription prior to radiation administration must be clearly written, dated and signed by the authorized person;

3. Patient identity must be verified by more than one method;

4. Final plans and calculations for brachytherapy and teletherapy in accordance with written directives/prescription must be completed before 25% of the dose is administered;

5. A weekly review of patients during radical treatment should be undertaken by responsible medical personnel and any unusual response evaluated as a possible indication of treatment error;

6. A complete treatment record with data recorded at the time of treatment, and treatment charts for fractionated treatment must be checked for completeness and accuracy weekly;

7. A procedure must be in place for ensuring the accuracy of data used in radiation planning or treatment.

Based on survey findings (Appendix A), the great majority of institutions have their own quality assurance program and procedures in radiation therapy. For the few that do not have a complete quality assurance program, Phase I would allow the development of an individual quality assurance program with local quality control procedures, as long as these procedures meet the national standards.

It must be emphasized that most of the required quality control procedures and required procedural elements have been detailed in existing published standards. The task in Phase I is to recommend the overall structure and primary elements of the set of Canadian standards and to list and authorize the use of selected quality assurance and quality control procedures.

Once a set of national standards for radiation therapy quality assurance has been developed, a peer review program to audit compliance with the national standards should be established, and if necessary, compliance with the national standards can be made a condition of the AECB licence.

4.1.2 Peer Auditing and Audit Reporting

Peer auditing is a necessary component of a good quality assurance program. It is recognized that many radiation therapy centres now have audits of selected parts of their programs by various groups. There is not, however, a comprehensive evaluation of the quality assurance program. In the past this has not been possible since there have not been standards against which to evaluate the program. Once the standards have been promulgated, auditing teams representing all of the professionals in the radiation therapy program should be appointed. These groups would visit each radiation therapy centre to evaluate compliance with the new standards. The cost of these visits would be borne by the individual radiation therapy centres. To minimize the impact of this auditing process it is recommended that the auditing visits be coordinated, where possible , with the accreditation visits of the CCHSA.

A standard procedure for peer auditing criteria needs to be developed, and the qualifications of acceptable peer auditors established. The recommended frequency of peer audits should be agreed.

The basic questions to be answered by the auditing team are: Is the radiation therapy centre operating a quality assurance program which complies with the national standards? If not, what are the areas of non-compliance and how can these be corrected?

Before the auditing team can begin to assess compliance auditing forms should be developed. It is recommended that these follow the format developed by the CCHSA for their accreditation process. Also, the auditing teams should evaluate their forms and their procedure by performing a "mock" audit of a radiation therapy centre before an actual audit is conducted. It is recommended that the actual audit be conducted at the time of the accreditation visit by the CCHSA. If a radiation treatment centre is not participating in the CCHSA accreditation process then it will be necessary to schedule an independent visit of the audit team. The report of the auditing team should be submitted to the CARO and also to the AECB as verification of compliance with the licence requirements.

The GMA suggests that peer audit teams be composed of an appointed CARO or Association des radio-oncologues du Québec (AROQ) radiation oncologist, COMP or L'association des physiciens et ingénieurs biomédicaux du Québec (APIBQ) medical physicist, Canadian Association of Medical Radiation Technologists (CAMRT) or L'ordre des technologues en radiologie du Québec (OTRQ) radiation therapist. In some cases it may be necessary to include other specialists who perform radiation therapy procedures. It will be necessary to ensure that the team has a detailed knowledge of radiation therapy and that the team members are educated about correct auditing practice.

4.2 PHASE II - Database of Incidents and Risks

The expert team assembled to produce the Canadian quality assurance standards should also be asked to finalize the criteria for *Recordable* and *Reportable* events and to recommend a standard format for reporting of these events. The goal in this phase is two-fold - first, to produce a national database

of significant incidents and risks which can be disseminated electronically to the appropriate persons at each treatment centre and second, to produce a database of recordable events and reportable events over a two year time period for the purpose of risk analysis.

4.2.1 Recordable Events

The GMA defines a *Recordable* event as any loss of control of a system involved in the delivery of a prescribed radiation dose when this loss of control results in a deviation from the intended procedures during a course of radiation therapy.

4.2.1.1 Criteria for Recordability

A *Recordable* event implies that a mistake in the procedures to be followed during administration of radiation has occurred. The following criteria are given as examples of *Recordable* events:

1. Radiation treatment without a written directive where a written directive is required.
2. Radiation treatment where a written directive is required without daily recording of each administered radiation dose in the appropriate record.
3. A teletherapy radiation dose when the calculated weekly administered dose differs from the weekly prescribed dose by 15 percent or more of the weekly prescribed dose.
4. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 15 percent of the prescribed dose with the exception of cases where the distribution was noted and accepted by the radiation oncologist.

This list is not comprehensive; further consultation with national professional bodies is necessary to arrive at a comprehensive list.

4.2.1.2 Local Record Keeping (Log book)

If reasonable standards of local record keeping and central reporting are implemented a valuable pool of data from all centres will evolve. Record keeping should be carried out in a uniform fashion to facilitate data pooling. During the first two years, log books would be submitted at six month intervals. Formal analysis of the pooled data from *Recordable* events in all treatment centres would guide future improvements in both the quality and safety of radiation therapy delivery. The Canadian Institute for Health Information (CIHI) is an existing organization that should be approached to collect and analyse the data submitted from individual centres.

Each radiation therapy centre should keep a record in a standard format of the deviation of any procedure outside the specified limits. The GMA suggests the following minimum data set for *Recordable* events to be included in a detailed report form and entered in the log book:

Patient name and any other identifiers
Diagnosis
Site of treatment
Prescribing Physician
Machine type and manufacturers identification
Prescribed dose
Actual dose
Method of measurement or estimation of actual dose.
Details of the event which led to incorrect dosage or procedure (e.g., wrong patient or wrong site)

4.2.2 Reportable Events

Of the *Recordable* events saved in any treatment centre, a subset of more serious errors would also be *Reportable* individually to a central database. It is highly desirable to have a uniform approach in the format and data to be included as *Reportable* events. Also, it is suggested that all *Reportable* events of radiation therapy be reported in a timely fashion by the radiation program director at the radiation treatment facility to a central agency. *Reportable* events will generally be errors in dose delivery. Also to be reported are equipment design flaws or procedural problems which would likely produce large single or systematic errors in dose delivery.

4.2.2.1 Proposed Criteria for Reportability

The GMA proposes the following criteria as an indication of the type of error to be considered *Reportable* to a central organization. Further consultation with national professional bodies is necessary to arrive at a comprehensive list. A *Reportable* event implies that a major mistake in the administration of radiation has occurred and may involve:

1. A teletherapy radiation dose prescribed for one patient:

(i) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;
(ii) When the calculated weekly administered dose differs from the weekly prescribed dose by 30 percent or more of the weekly prescribed dose;
(iii) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose with the exception of cases where the distribution was noted and accepted by the radiation oncologist.

2. A brachytherapy radiation dose prescribed for one patient:

(i) Involving the wrong individual, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
(ii) Involving a sealed source that is leaking;
(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure;

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose with the exception of cases where the distribution was noted and accepted by the radiation oncologist.

3. Systematic errors in dose delivery where the total administered dose delivered to a series of more than 5 patients differs from the total prescribed dose by 10% or more.

4. Equipment design faults or procedures which would likely lead to errors as listed in 1, 2 or 3 above.

The GMA suggests that the following factors also be considered in the formulation of the final definitions of reportability:

- whether the error occurred in the course of curative or palliative treatment
- whether the deviation resulted from machine malfunction or human error
- whether or not the error caused harm to a patient
- the number of patients potentially harmed or affected
- the correctability of the error within the course of treatment for a single patient.

The final criteria for *Reportable* and *Recordable* events should be determined by the group of experts which is assembled to write the national quality assurance standards.

4.2.2.2 Reporting the Reportable Events

The following are suggested procedures to follow for notifying appropriate persons after a *Reportable* event has been discovered.

1. Following the discovery of a *Reportable* event, the radiation program director should notify the selected national body within 2 working days, followed by a written report within 3 weeks. The report should include a brief description of the event, why it occurred, what improvement/action is needed to prevent a recurrence, whether or not the responsible physician notified the patient/guardian/relative and if not, why not, and what information was provided to them. The report should not include any information which may lead to identification of the patient or physician.

2. The radiation program director shall ensure that the responsible physician notifies the referring physician (usually a surgeon or general practitioner) of the *Reportable* event no later than 2 working days after its discovery. Appropriate medical or remedial care should not be delayed.

3. Each radiation program director shall retain a record of each *Reportable* event for the lifetime of the patient. The record must contain the names of all the people involved, including the identification of the patient; description of the event; the effect on the patient and the improvement or action needed or taken to prevent a recurrence.

4. The radiation program director should notify the designated national body as soon as possible if a desig. flaw or a method of usage of the planning or treatment equipment which has the potential to cause a *Reportable* Event is discovered.

4.2.2.3 Dissemination of Information Regarding Reportable Events

It is important that information about *Reportable* events be disseminated as quickly as possible when there is the potential for a similar incident at another centre. This is particularly important when equipment malfunction is involved.

Upon receiving notification of a *Reportable* event, including a design or procedural flaw which might lead to a *Reportable* event, and which might affect patient care in other centres, the designated national body would immediately inform the radiation program directors and heads of medical physics at all radiation therapy centres in Canada of the incident.

4.3 PHASE III - Risk Analysis

Phase II would provide the data necessary to make an estimate of the risks of misadministration in radiation therapy. In Phase III the analysis of this data would be done and the report of this analysis would then be reviewed by professional bodies and other stakeholders. If the justification for further monitoring of quality assurance programs is not found, then the submission of logs of *Recordable* events would be discontinued. The reporting of *Reportable* events implemented in Phase II, however, would remain in place.

4.4 PHASE IV- Continued Submission of Recordable Events

If Phase III risk analysis demonstrates that the frequency or severity of radiation therapy misadministration is larger than anticipated or that the problem requires further study then it will be necessary to continue to collect logs of recordable events. In addition, there would be a review of the adequacy of the national standards to ensure that the risks identified are being correctly addressed.

5.0 SUMMARY AND CONCLUSIONS

This report identifies several issues to be considered in the design of a national quality assurance program for radiation therapy centres and also describes several problems with the procedures that are presently followed in Canada. Many of the problems stem from the lack of a national structure for quality assurance and a formalized national consensus on quality standards. The quality of radiation treatment in Canada is perceived to be high and this is undoubtedly the case. However, due to the increasing complexity of radiation therapy and the consequences of significant errors in dose delivery it is essential that written national standards in radiation therapy quality assurance be developed and promulgated. Also, to minimize the risks of misadministration due to equipment or procedural design flaws, a national database of significant incidents and risks should be established.

The major recommendations of this report are:

1. There should be a single Canadian body empowered to licence and monitor the use of all radiation therapy treatment and simulation equipment in Canada. If existing regulatory bodies are used, their efforts must be coordinated and extended.

2. A group of experts should be appointed to develop Canadian Standards for Quality Assurance in Radiation Therapy based upon existing accepted standards. The standards should be maintained and promulgated by a group such as the Canadian Association of Radiation Oncologists.

3. A peer auditing process should be developed to monitor compliance with the Canadian Standards for Quality Assurance in Radiation Therapy.

4. If necessary, compliance with the Canadian Standards for Quality Assurance in Radiation Therapy should be made a condition of the licence issued by the Atomic Energy Control Board to radiation therapy centres.

5. An electronic bulletin board should be established to disseminate information about significant incidents and risks in radiation therapy. A group such as the Canadian Organization of Medical Physicists should maintain this facility.

6. A system should be developed or adopted to ensure the safety of all equipment, including ancillary and accessory equipment, before it reaches the end user, if a failure of that equipment would pose a significant threat to patient safety.

7. Data should be collected from all Canadian radiation therapy centres and analyzed to determine the frequency and severity of misadministrations in Canada. This database should be established and the analysis conducted by the Canadian Institute of Health Information.

A major difficulty in developing a national program for quality assurance is the determination of the appropriate national bodies to be responsible for the national standards and to act as keepers of the national database. Although several agencies have been suggested in this report for these roles it is not clear that these agencies will be willing to take on this responsibility. Every effort should be made to seek their cooperation.

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APPENDIX A

SUMMARY OF SURVEYS

In 1994, AECB was interested in knowing licensees opinion on patient safety in Radiation Therapy. Letters were sent out and an advertisement placed in the "AECB Reporter" requesting their views on this matter.

Replies were received from the following:

1. Canadian Association of Radiation Oncologists (R.N. Fairey)
2. Cross Cancer Institute, Edmonton (Sandra Richardson)
3. Vancouver General Hospital (John Aldrich)
4. The Manitoba Cancer Treatment and Research Foundation (David A. Viggars)
5. Ontario Ministry of Health, HARP Commission (Susan Elworthy)
6. Ottawa Regional Cancer Centre (L.H. Gerig)
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9. British Columbia Cancer Agency (Ellen El-Khatib)
10. National Research Council Canada (D.W.O. Rogers)
11. Canadian Organization of Medical Physicists (Geoffrey W. Dean)
12. Ordre des Technologues en Radiologie du Québec (Johanne Bergeron)
13. Health Canada, Deputy Minister (Michèle S. Jean)
14. Hamilton Regional Cancer Centre (Marcia Smoke)

There was interest expressed in this subject. Opinions ranged from against more "rules and regulations" to support of AECB involvement:

> "AECB is the best agency to address patient safety issues"; "The AECB is an independent agency from the Cancer Centres thus making it an appropriate group with no bias to address patient safety."

Between the extremes of no involvement at all and specific detailed regulation of patient safety in radiation therapy, there was the suggestion that the establishment and implementation of a uniform code of practice might be a worthwhile and deliverable outcome of the AECB's current involvement of this issue.

Patients and/or Public (Clients) views were not requested.

In May 1996, a survey letter on Quality Assurance was sent from M. Lupien on behalf of the GMA to thirty two (32) chief radiation oncologists with AECB radiation therapy licences, Provincial/Territory Colleges and to the Canadian Council on Health Services Accreditation. These are the questions requested from the radiation oncologists (Questions were modified accordingly):

1. Does your facility have a specific quality assurance program or procedures for the overall delivery of radiation therapy? If so, could you provide us also with a copy of your present program or procedures?

2. When was the last time this Quality Assurance program or procedures was updated?

3. Are external audits carried out to test the quality assurance program/procedures? If so, when and how often?

Comments and responses were received from the following radiation therapy licensees (non-response from 15 licensees):

1. Queen Elizabeth Hospital - P.E.I. (W.T. Hooper)
   - no existing program

2. B.C. Cancer Agency - Fraser Valley Cancer Centre (John French)
   - existing quality assurance program: 2 external audits carried out so far by M.D. Anderson TLD Dosimetry service and by external physicist

3. Northeastern Ontario Regional Cancer Centre - Sudbury (Tai K. Yeung)
   - QA Committee -- subcommittee of Radiation Treatment Program Management Team. Chart reviewed, treatment plan reviewed. Incident report system and external audit for dosimetry on annual basis.

4. Manitoba Cancer Treatment and Research Foundation (David A. Viggars)
   - QA mostly in Technical Quality Assurance. QA in radiation therapy program is being further developed, extend audit - physics department participates dosimetry. Annual comparison with M.D. Anderson; RTOG and National Cancer Institute of Canada (NCIC) inpatients on Protocol.

5. Hamilton Regional Cancer Centre (Tom Farrell)
   - Radiation Therapy Accuracy and Safety Committee (RTASC) oversees the quality assurance program. Some external review as part of accreditation of the regional centre.

6. Centre universitaire de santé de L'Estrie (Luc Ouellet)
   - Existing physics services quality assurance program.

7. Saskatoon Cancer Centre (M.F. Mohamed)
   - Existing physics services quality assurance procedures. Radiation treatment guidelines being developed. Universal occurrences reporting system. Multiple chart reviews and multi-disciplinary rounds.

8. Tom Baker Cancer Centre - Southern Alberta Cancer Program (Patricia Fisher)
   - Cross section QA procedures, more of it comes under medical physics coverage
   - External audits associated with accreditation, CCHSA

- External audits also exist with protocol participation with RTOG, NCIC, and the National Surgical Adjuvant Breast Program (NSABP)
- Patient reviews

9. University of Guelph - Environment Health and Safety Department (Geoffrey G. Byford)
   - Deals with co-unit associated with the Veterinary College. "The Cobalt-60 radiation therapy unit at the Ontario Veterinary College in now used only occasionally due to budget constraints."

10. Cross Cancer Institute - Northern Alberta Cancer Program (R.G. Pearcey)
   - Has quality assurance program for its overall delivery of radiation therapy. Its "policy and procedures" include all facets of radiation therapy including misadministration and its related reporting procedure. There is no formal external audit but accreditation is carried out once every three years through Canadian Hospital Association and the quality assurance program is reviewed. Participation of RTOG clinical trail also contributes to the audit of dosimetry.

11. Thunder Bay Regional Cancer Centre (Bans Arjune)
   - Thunder Bay has QA program mainly related to machine/physics checks. It has daily, weekly, monthly, and yearly mechanical checks. External QA audit was carried out by the Radiological Physics Center (RPC) and other visiting medical physicists.

12. Allan Blair Cancer Centre - Saskatchewan (L.A. Firth)
   - It has provided the "Physics Services Quality Assurance Manual". It contains all aspects of physics, dosimetry, block compensators, planning, software, etc., as related to radiation therapy. External audits also exist with protocol participation with RTOG, NCIC, NSABP.... Treatment reviews.

13. The Sir Mortimer B. Davis - Jewish General Hospital (Micheline Gosselin)
   - A quality assurance program/procedures for the overall delivery of radiation therapy has been established since 1990. It deals with preventive maintenance, performance check procedure of radiation therapy equipment; the checking of charts and calculations and treatment chart screen which is performed by the Chairman of the Quality Assurance Program on a monthly basis. There are no external audits.

14. Montreal General Hospital - McGill (Carolyn Freeman)
   - Has QA Program that comprises all aspects of the delivery of treatment with irradiation including regular machine checks and calibration, review of clinical and technical date of radiation treatments and unusual toxicity and evaluation of outcome and misadministration reporting. External audits carried out through participation of protocols in clinical trials.

15. Newfoundland Cancer Treatment and Research Foundation (Dilip Panjwani)
   - Has radiation therapy policy and procedure manual with emphasis on machine checks and calibration. No existing external audits.

16. Kingston Regional Cancer Centre (Peter Dixon)
    - Has specific quality assurance programs in radiation therapy.

17. British Columbia Cancer Agency - Vancouver Cancer Centre (Thomas J. Keane)
    - Has specific quality assurance procedures in radiation therapy equipment commissioning and in patient treatment planning procedures. Quality Improvement Committee meets monthly to review radiation therapy processes and treatment policies derived from different tumour groups.

From the responses, it is quite clear that a great majority of facilities have a Quality Assurance Program in which physics departments have major responsibilities in machine performance, regular maintenance, planning and dosage calculations, etc. Many audits were carried out with CCHSA and also through protocol participation and physics audit.

Comments and responses were received from the following provincial/territory colleges.

1. New Brunswick (Ed Schollenberg)
2. Saskatchewan (L.M. Loewen)
3. Yukon (Elsie Bagan)
4. Prince Edward Island (H.E. Ross)
5. Nova Scotia (Cameron D. Little)
6. Alberta (B.D. Ward)
7. British Columbia (T.F. Handley)
8. Québec (Joëlle Lescop)
9. Newfoundland (Robert W. Young)
10. Northwest Territories (Paula Lessard)
11. Manitoba (Linda B. Beaiiun)

There is no direct involvement of the colleges in patient safety in radiation therapy but any complaint would be investigated. The Manitoba College did send along the Manitoba Quality Assurance Program (MANQAP), but this was not directly applicable to radiation therapy safety to patients.

The Canadian Council on Health Services Accreditation does not have standards on the accreditation of radiation therapy facilities. However, CCHSA does have a manual on the Standards for Cancer Treatment Centres - A Client-centred Approach, which is more an approach to the overall treatment of patients. Integrated audit similar to the inspection of a hospital pharmacy have been discontinued and transferred to the Province or Territory. CCHSA has now reverted to its earlier mandate of writing norms and guides.

APPENDIX B

Recommendations from the Report "Quality Assurance in the Use of Ionizing Radiation in Canadian Medical Institutions" (INFO–0665)

1. The AECB should take an active role in the optimization of protection in medical exposures.

2. The AECB should initiate discussions with Health Canada to agree on which agency should take the lead role in coordinating federal regulation of the design and operation of equipment which emits ionizing radiation.

3. The AECB should accept responsibility for coordinating the regulation of all practices giving rise to occupational, public and patient exposures in medical institutions.

4. The AECB regulatory strategy should be one of writing general regulations requiring that quality assurance programs be put into effect but leaving the establishment of appropriate guidelines or Codes of Practice for these programs to working groups representing professional bodies whose members are involved in the technologies which utilize ionizing radiation in medical institutions.

5. Codes of Practice in radiation protection should be established for each of the major technologies using ionizing radiation in medical institutions.

6. Appropriate Codes of Practice should be developed from the generic models of the International Standards Organization, the ISO 9000 series.

7. The AECB should take the initiative to recommend a Canadian system for the reporting of incidents and accidents in the medical uses of ionizing radiation.

8. There is an urgent need in hospitals for a document outlining the fundamental characteristics of a radiation safety programme to include outline of programme; reporting/management structure; incident/accident definitions and reporting criteria; and what an ALARA programme entails. The AECB should immediately initiate the preparation of a document for this purpose.

APPENDIX C

Incidents in Radiation Oncology

	Event	Consequence	Reference	Comment
1	Loss of HDR Ir-192 Source, Indiana Regional Cancer Center, Indiana, Pennsylvania, 1992	Overdose and death of 1 patient, exposure to 94 people	Paperiello CJ: Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center, Indiana Pennsylvania, on November 16, 1992. NUREG-1480. US NRC, 1993	Led to requirement for hand-held radiation monitoring of HDR patients at treatment completion
2	Isocentric monitor unit calculation system error, North Staffordshire Hospital Centre, Stoke-on-Trent, Britain, 1982-1991	Roughly 1000 patients received 30% less dose than prescribed	Report of the Independent Inquiry commissioned by the West Midlands Regional Health Authority into the conduct of Isocentric Radiotherapy at the North Staffordshire Royal Infirmary between 1982 and 1991, August, 1992; BBC TV News, February 7, 1992; Second Report of the Independent Inquiry commissioned by the West Midlands Regional Health Authority into the conduct of Isocentric Radiotherapy at the North Staffordshire Royal Infirmary between 1982 and 1991, March, 1994.	Monitor unit calculations need to be checked using an independent system
3	HDR Misadministrations, U. Wisconsin, 1991	No noticeable effect on the patients, but reported as misadministrations	Thomadsen BR, et al: Anatomy of two HDR misadministrations (Abstract). Medical Physics 18(3): 645, May/June, 1991	Plan each HDR case with two members of the physics staff. Check each HDR case by a third, independent member of the physics staff
4	Linear accelerator operated at maximum electron energy (36 MeV) no matter which electron energy was selected due to incorrect repair, Clinical Hospital of Zaragosa, Spain, December, 1990	27 patients irradiated excessively, leading to 3 deaths	The accident of the linear accelerator in the Hospital Clinico de Zaragosa, a report of the Spanish Society for Medical Physics, August, 1991	Output checks and energy checks should be performed at regular, defined intervals and after linear accelerator re-
5	Applying the wedge factor twice; Rochester General Hospital, May to August, 1988	Overdoses to 24 patients, from 10% to 50%	Radiology & Imaging Letter (Special Supplement 13), December 1, 1988; Eisenberg C: Wrong radiation doses given, Rochester Democrat Chronicle Times-Union, Sep 15, 1988; Smith SJ: Wrong data led to overdoses. Rochester Democrat Chronicle, Sep 20, 1988	Providing a system including the independent check of each monitor unit calculation should lessen the chances of
6	Cobalt calibration error, Exeter Hospital, England, 1988	153 patients given 25% overdose	Tobias J: What went wrong at Exeter? Br Med J 297:372-3, Aug 1988	Calibrations need independent check

7	Incorrect use of time calculation program, Sacred Heart Hospital, Cumberland, Maryland, October, 1987 to November, 1988	75% overdoses of radiation to 33 patients, perhaps 20 deaths	Epstein KC, Wendling T: Maryland releases files amid outcry. Cleveland Plain Dealer, December 19-20, 1992	Time calculations need independent check
8	Time calculation error on a single patient treatment, Alta-Bates Medical Center, Berkeley, California, 1987	100% overdose, patient died	Wendling T, Davis D: Dangerous Medicine, Deadly Mistakes. Cleveland Plain Dealer, December 13-28, 1992; CBS Evening News, April 5, 1993	Time calculations need independent check
9	Abandoned Cs-137 Teletherapy source acquired and dismantled by junk metal dealer, Goiania, Brazil, September 13, 1987	4 deaths, several injuries	Roberts L: Radiation Accident grips Goainia, Science 238(4830): 1028-1031, Nov 20, 1987; Maletskos CJ(ed): The Goiania Radiation Accident. Health Physics 60(1)(Special Issue) Jan, 1991	Thorough source tracking and accountability is necessary
10	Time calculation error, involving use of inverse-square, on a single patient treatment, Cleveland Clinic, Cleveland, Ohio, 1986	70% overdose, patient died	Wendling T, Davis D: Dangerous Medicine, Deadly Mistakes, Cleveland Plain Dealer, December 13-28, 1992	Time calculations need independent check
11	Therac 25 Incidents, from June 1985 to January, 1987	Six separate overdose incidents, three of which led to patient deaths	Leveson NG, Turner CS: An investigation of the Therac-25 Accidents. Computer 26:18-41, July, 1993; ABC TV newsmagazine, 20-20, July 2, 1987	
12	Co-60 source acquired and dismantled by junk metal worker. Juarez, Mexico, December, 1983	200 people exposed to doses from 1 to 50 rem	Marshall E: Juarez: An unprecedented radiation accident. Science 223:1152-1154, Mar 16, 1984	Thorough source tracking and accountability is necessary
13	Error in calibration of linear accelerator due to incorrect reading of barometric pressure, St. Charles Medical Center, Bend, Oregon, 1982	14% overdose to 600 patients	Jwasaki J: Officials say error at hospital 'major'. Bend Bulletin, Aug 17, 1986; Wright BA. et al: Barometric pressure obtained from the National Weather Service at a local airport. AAPM Bulletin 11(4):3, Sep/Oct, 1986	Each parameter involved in a calibration needs independent check
14	Cobalt calibration error, Riverside Methodist Hospital, Columbus, Ohio, 1975-6	400 patients overdosed up to 40%	Rubin LS: The Riverside radiation tragedy. Columbus Monthly 3(4):52-66, April 1975.	Calibrations need independent check

Reference: Rosemark, P. Incidents in Radiation Oncology, AAPM/SCC Newsletter, May 1996 [Ro96].